UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE GPC BIOTECH AG SECURITIES LITIGATION	:	ECF Case 07-CV-06728 (DC)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

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Defendants GPC Biotech AG ("GPC"), Bernd R. Seizinger, Mirko Scherer, Elmar Maier, and Sebastian Meier-Ewert hereby move pursuant to Fed. R. Civ. P. 12(b)(6), Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA") to dismiss Plaintiffs' Consolidated Class Action Complaint (the "Complaint" or "Cmp."). Plaintiffs' allegations fail to support any of their claims, which are asserted under Sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a) and 78t-1(a), respectively.[1]

PRELIMINARY STATEMENT

This securities fraud case stems from a July 24, 2007 vote by the Oncologic Drugs Advisory Committee ("ODAC") of the Food and Drug Administration ("FDA") to delay action on GPC's application for accelerated approval of a cancer drug known as satraplatin.

That application sought FDA approval to market satraplatin as a second-line treatment of hormone-refractory prostate cancer (or "HRPC") in patients whose disease had progressed after first-line chemotherapy. A multi-year clinical study involving 950 patients and conducted in 170 clinical centers in 16 countries demonstrated that satraplatin is highly effective in treating HRPC as measured by "progression-free survival" ("PFS"), a study endpoint that examines the drug's effect on the progression of the disease.

Plaintiffs' claims rest on three core allegations: (1) that the FDA advised GPC early in the drug development process that achieving the study's PFS endpoint (as opposed to an

[1] Defendants note that the Complaint as written only brings claims against the individual Defendants, Cmp. ¶¶131-46, although GPC is alleged to be a "Defendant." Id. ¶¶1, 30. Accordingly, the claims against GPC should be dismissed because, notwithstanding the lengthy allegations referencing its conduct, it is not included in the three counts asserting violations of the federal securities statutes. Out of an abundance of caution, GPC has been included in the arguments made on behalf of Defendants, which apply with equal force to it as well as to the individual Defendants.

endpoint measuring satraplatin's effect on overall survival of the study's participants) would not by itself be sufficient evidence of satraplatin's efficacy to warrant accelerated approval of the drug; (2) that GPC nonetheless engaged in what it knew was a futile attempt to obtain accelerated approval based on a PFS endpoint without disclosing to investors that the FDA had already rejected the sufficiency of that endpoint; and (3) as was preordained, that the FDA did in fact "reject" GPC's accelerated approval application because of its reliance on PFS trial results.

Defendants have moved to dismiss the Complaint because its allegations do not satisfy the stringent pleading requirements established by the PSLRA and Fed. R. Civ. P. 9(b) and, indeed, would not state a viable cause of action even under a pleading standard far more forgiving. This is true for at least the following reasons.

First, the pivotal allegation of the Complaint – that the FDA told GPC that it would not grant accelerated approval based on a PFS endpoint – could not be more conclusory. Plaintiffs have not pleaded a single fact that supports this naked allegation, including any of the facts they necessarily would know if they had a basis for making the allegation. The one attempt they do make to identify a source for it – paraphrasing an FDA document raising certain questions about GPC's application – is an indefensible mischaracterization of the contents of that document, an unmistakable sign that Plaintiffs' entire case is just the sort of concoction that led Congress to enact the PSLRA. Even more damning, that same document, as well as another FDA document cited in the Complaint, clearly demonstrates that the FDA ***did*** regard a PFS endpoint as an acceptable basis for accelerated approval of satraplatin and that, even on the last day of the alleged class period (and possibly after that[2]), the FDA was in fact actively considering granting

[2] An ODAC vote on an issue presented to it by the FDA is advisory and does not bind the agency. *See* May 15, 2007 Press Release (cited at Cmp. ¶93), attached as Exhibit 6 to the Affidavit of Bernard J. Garbutt III sworn to May 14, 2008 (the "Garbutt Aff.").

accelerated approval based on the positive PFS trial results submitted by GPC.

Second, the Complaint is also legally deficient because it fails to allege loss causation, an essential element of Plaintiffs' claims. Rather than affirmatively establish the necessary causal connection between the alleged fraud and the stock price decline responsible for their alleged losses, Plaintiffs unwittingly do just the opposite by citing two FDA documents, both of which unambiguously demonstrate the absence of loss causation. As those documents show, the approvability questions that the FDA raised when it released its public commentary on the application, and the issues that led ODAC to vote to delay a decision on it (those being the two events triggering the drop in GPC's stock price), had nothing whatsoever to do with any FDA doubts about PFS's suitability as a basis for accelerated approval. Consequently, the Complaint must be dismissed because Plaintiffs have not satisfied, and cannot satisfy, the element of loss causation.

Third, Plaintiffs also fail to allege facts giving rise to a strong inference that Defendants acted with scienter (which is not surprising given Plaintiffs' failure to allege any false or misleading statements in the first place). Plaintiffs' attempt at meeting this requirement by alleging "conscious misbehavior" on Defendants' part is deficient, first, because Plaintiffs' allegation that Defendants possessed undisclosed adverse information about satraplatin's approvability is, once again, completely conclusory and, second, because the Plaintiffs do not even allege that the individuals accused of making the allegedly false and misleading statements in question were aware of that adverse information. Moreover, Plaintiffs' effort to plead scienter by asserting that Defendants had a motive and opportunity to defraud investors fares no better. The courts have repeatedly and consistently held that the motives that Plaintiffs attributes to Defendants (*e.g.*, a motive to raise capital) are legally insufficient to support a finding of scienter

or that Plaintiffs have inadequately pled them.

Finally, Plaintiffs' remaining claims against the individual Defendants are defective because, as set forth above, Plaintiffs have failed to allege a primary violation of the Exchange Act, have failed to plead any culpable conduct at all as required for the Section 20(a) control person claim, and have not (with one exception) pleaded the contemporaneous trades of shares between Defendants and Plaintiffs as required to state a claim under Section 20A of the Exchange Act.

Each of these clear and incurable flaws in the Complaint is by itself fatal to Plaintiffs' case. Accordingly, Defendants respectfully request that this Court enter an Order dismissing Plaintiffs' Complaint with prejudice.

THE RELEVANT ALLEGATIONS OF THE COMPLAINT[3]

I. BACKGROUND

GPC is a German company headquartered in Munich. It wholly owns a United States subsidiary located in Princeton, New Jersey. Cmp. ¶30. GPC's common stock trades on the Frankfurt (Germany) Stock Exchange. It also sponsors American Depositary Receipts evidencing American Depositary Shares that are traded on the NASDAQ Global Market. Cmp. ¶31. Defendant Seizinger is Chief Executive Officer of GPC. During the relevant period, Defendant Scherer was GPC's Chief Financial Officer, Defendant Maier was GPC's Senior Vice President, Business Development, and Chief Operating Officer (for GPC Martinsried/Munich, Germany), and Defendant Meier-Ewert was GPC's Senior Vice President and Chief Scientific Officer. Cmp. ¶¶32-35.

[3] As required under Fed. R. Civ. P. 12(b)(6), Defendants accept Plaintiffs' well-pled factual allegations as true solely for purposes of this motion to dismiss, and will dispute them as appropriate should the case survive the motion to dismiss.

In 2002, GPC obtained the exclusive commercial rights to satraplatin, a platinum-based compound intended to treat cancer. Cmp. ¶46. Unlike all other currently-marketed platinum-based compounds, satraplatin is not administered intravenously and thus has the unique advantage of allowing patients to take it orally at home. Cmp. ¶30; *see* 20-F Report for period ended December 31, 2005 filed with the Securities and Exchange Commission ("SEC") ("2005 20-F") at 9, 26 (cited at Cmp. ¶¶72-73), Garbutt Aff., Exh. 1; 20-F Report for period ended December 31, 2006 filed with the SEC ("2006 20-F") at 27 (cited at Cmp. ¶95), Garbutt Aff., Exh. 2.

GPC acquired the rights to satraplatin with the intention of seeking FDA approval to market it for use in the treatment of several forms of cancer, including as a second-line treatment for HRPC in patients whose disease had continued to progress after first-line chemotherapy treatment. Cmp. ¶¶48, 62. As GPC informed investors, "[t]here is currently no approved second-line chemotherapy treatment for patients who fail first-line chemotherapy treatment for HRPC." 2005 20-F at 26.

II. THE FDA REGULATORY PROCESS FOR SATRAPLATIN

To obtain FDA approval to market a drug in the United States, the drug's sponsor must, among other things, conduct clinical trials to demonstrate that the drug is safe and effective. Cmp. ¶¶8, 50. In July 2003, GPC met with the FDA to discuss its design of Phase III clinical trials intended to establish that satraplatin is effective in treating HRPC. Cmp. ¶53. GPC proposed a trial, the "SPARC" (Satraplatin and Prednisone Against Refractory Cancer) trial that was intended to assess the efficacy and safety of satraplatin in combination with prednisone as a second-line treatment for HRPC in treating patients whose prostate cancer had progressed after first-line chemotherapy. Cmp. ¶58.

GPC sought accelerated approval of satraplatin. Cmp. ¶60. As GPC disclosed in its

2005 20-F, the accelerated approval process allows the FDA to approve a drug to treat serious or life-threatening illnesses based on surrogate endpoints, which "are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms," such as overall survival. 2005 20-F at 45, Garbutt Aff., Exh. 1. The final overall survival analysis could not be conducted in the SPARC trial until a pre-specified number of patients had died (700 patients according to the Complaint). Cmp. ¶102.

GPC used the surrogate endpoint of "progression free survival" or "PFS" in the SPARC trial "to measure the effectiveness of treatment in slowing down the progression of prostate cancer in patients taking the Satraplatin protocol." Cmp. ¶57. For purposes of this study, PFS was defined as a composite of several different factors: radiological progression, skeletal events progression, and the progression of other symptoms, such as pain, performance status, and weight loss. Cmp. ¶¶94, 104(1). As analysts noted in some of the reports Plaintiffs reference, "[a]lthough the composite endpoint [PFS] in the SPARC trial has not been used previously in registration trials, all of the [individual endpoints that were constituents of GPC's composite endpoint] each have been used in previous registration studies," and "PFS was accepted by the FDA . . . in other tumour indications" for other cancers. Deutsche Bank Analyst Report, dated July 22, 2007, at 4 (cited at Cmp. ¶108), Garbutt Aff., Exh. 7; DZ Bank Analyst Report AG, dated August 3, 2007, at 2 (cited at Cmp. ¶112), Garbutt Aff., Exh. 10 (referencing three other cancer drugs that were approved).[4]

The FDA allowed GPC to proceed with its Phase 3 clinical trial, and it granted "fast

[4] The Complaint refers to a DZ Analyst Report dated August 2, 2007, but the actual report is dated August 3, 2007.

track" designation to GPC's New Drug Application ("NDA") for satraplatin.[5] Cmp. ¶¶54, 56. Fast track designation is intended to facilitate the development, and expedite the review of, drugs for "serious or life-threatening conditions for which there is no effective treatment and that demonstrate the potential to address unmet medical needs." Cmp. ¶51; *accord* 2005 20-F at 32, Garbutt Aff., Exh. 1; 2006 20-F at 33, Garbutt Aff., Exh. 2. The FDA's "fast track" designation of satraplatin reflected the fact that no other drug had been approved for patients whose prostate cancer had progressed after first-line chemotherapy. Cmp. ¶54.

III. THE RESULTS OF THE SPARC TRIAL AND THEIR SUBMISSION TO THE FDA

In September 2003, GPC began enrolling participants in the SPARC trial. Cmp. ¶58. The SPARC trial involved 950 patients enrolled at approximately 200 clinical centers in 16 countries on 4 continents. Cmp. ¶73 (quoting 2005 20-F). By September 2006, the study data were showing statistically significant positive results for PFS, including 36% to 40% reductions in the risk of disease progression in patients who received satraplatin as compared to the control population. *See* Cmp. ¶¶77, 78, 82, 83, 85, 86, 89, 91, 94, 95; *see also* 2006 20-F at 32-33 (describing results of SPARC trial). Notably, Plaintiffs do not question any of the data that indicated, as they themselves allege, that satraplatin was "extremely effective" in slowing the

[5] Throughout the Complaint, Plaintiffs erroneously conflate the concepts and significance of "fast track" designation and "accelerated approval" of an NDA. "Fast track" designation invokes a process designed to facilitate the development and review of drugs that are intended to treat serious diseases and that fill an unmet medical need. 21 U.S.C. § 506(a). A drug given fast track designation is eligible for, among other things, more frequent meetings with FDA, more frequent written correspondence from FDA, and "rolling" submissions of its applications in sections rather than submission of the full application upon its completion. "Accelerated approval," on the other hand, is a mechanism through which a drug can receive approval based on data related to a "surrogate" endpoint rather than data related to a clinically meaningful outcome (the latter being required for full approval). 21 U.S.C. § 506(b); 21 C.F.R. § 314.510. A surrogate endpoint is an indirect or substitute endpoint that is deemed reasonably likely to predict a clinically meaningful benefit, such as survival. In the SPARC trial, the PFS endpoint was used as a surrogate for overall survival.

progression of prostate cancer. Cmp. ¶94.

Analysts noted that satraplatin offered significant potential benefits over the existing therapies, which had a less favorable side effect profile and could only be administered intravenously. *See* WestLB Analyst Report, dated January 19, 2007, at 9 (cited at Cmp. ¶84), Garbutt Aff., Exh. 3 (Because "the health status of many patients does not allow them to take Taxotere, or any other currently used chemotherapy, due to the side-effect profile and the fact that these drugs have to be given as intravenous injections," satraplatin represents an important treatment alternative "given its benign side-effect profile and its oral application route.").[6]

On February 15, 2007, GPC completed its submission of the NDA for satraplatin, which included the positive PFS clinical results from the SPARC trial. Cmp. ¶85. The FDA accepted the NDA for satraplatin and informed GPC that the NDA would be reviewed on an expedited basis. Cmp. ¶90.

IV. THE JULY 24, 2007 ODAC MEETING

The FDA decided to have GPC's NDA reviewed by ODAC. Cmp. ¶93 (citing GPC's May 15, 2007 press release). "Advisory committees provide the FDA with independent advice from outside experts on issues related to human drugs and other regulated areas. Although the committees provide advice to the agency, final decisions are made by the FDA." May 15, 2007 Press Release at 1, Garbutt Aff., Exh. 6; *accord* 2006 20-F at 34, Garbutt Aff., Exh. 2.

On July 20, 2007, the FDA issued a briefing document in which it identified issues raised by GPC's NDA on which it sought ODAC's advice (the "FDA Briefing Document"). Cmp.

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[6] *Accord* Credit Suisse Analyst Report, dated February 14, 2007, at 2-3 (cited at Cmp.¶87), Garbutt Aff.; Exh. 4 ("many patients do not want to start treatment with Taxotere, due to a poor quality of life/clinical benefit ratio." Patients have to balance the "extra 2.5 months with the intense dosing regime and the severe . . . side effects."); Pacific Growth Equities Analyst Report dated February 26, 2007 at 4 (cited at Cmp. ¶88), Garbutt Aff., Exh. 5 (noting benefit of satraplatin's "mild side effect profile" and "oral route of administration").

¶101; FDA Briefing Document, Garbutt Aff., Exh. 8.[7] The FDA Briefing Document posed several questions about the SPARC study, its methods and clinical results, and the advisability of approving satraplatin at that time. *Id.*; FDA Briefing Document at 3-4. Nothing in the FDA Briefing Document suggests that the FDA at any time regarded PFS as an unacceptable or inappropriate endpoint for the SPARC trial or that FDA ever communicated such to GPC. In relevant part, it stated only that "[t]he FDA [had] no prior experience with" the particular composite PFS endpoint used in the SPARC trial and that it would seek ODAC's advice concerning the acceptability of that particular composite PFS endpoint as the basis for marketing approval. *Id.*

Some of the issues raised in the FDA Briefing Document were discussed at a July 24, 2007 ODAC meeting. Cmp. ¶¶102-104. At the conclusion of that meeting, ODAC voted to delay action on GPC's application for accelerated approval until final overall survival data from the SPARC trial became available. Summary Minutes of the Oncologic Drugs Advisory Committee July 24, 2007 ("Summary Minutes")[8] at 8, Garbutt Aff., Exh. 9. According to the minutes of that meeting, ODAC did not, before taking the vote, address whether PFS, as defined for purposes of the SPARC trial, was an acceptable basis for approval of GPC's application.

On July 30, 2007, GPC announced that it had withdrawn its application for accelerated approval of satraplatin. Cmp. ¶111. At the time of the application's withdrawal, the FDA had not yet either granted or denied it.

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[7] The Complaint alleges that, on July 20, 2007, ODAC "issued preliminary comments in advance of the July 24, 2007 meeting with the Company." Cmp. ¶101. This allegation actually appears to refer to the FDA Briefing Document by which the FDA sought an advisory opinion from ODAC on the NDA for satraplatin. *See* FDA Briefing Document. Thus, this document does not reflect ODAC's comments at all, but rather consists of questions from the FDA on which it seeks ODAC's advice and input.

[8] The Complaint refers to the Summary Minutes as "[t]he ODAC report." Cmp. ¶104.

ARGUMENT

I. PLAINTIFFS' ALLEGATIONS OF FRAUDULENT CONDUCT ARE NOT PLED WITH THE SPECIFICITY REQUIRED BY THE PSLRA OR FED. R. CIV. P. 9(B)

A. The Complaint's Key Allegation – That The FDA Told GPC It Would Not Grant Accelerated Approval Based on a PFS Endpoint – Is Wholly Conclusory and Should Therefore Be Disregarded by the Court.

The lynchpin of Plaintiffs' case is their oft-repeated allegation that the FDA told GPC early in the development cycle that PFS "***could not*** serve as a primary endpoint and ***would not***, on its own, lead to approval of the Company's NDA on an expedited basis." *E.g.*, Cmp. ¶¶ 12, 14, 15, 56 (emphasis added). Without this allegation, their case is not viable because, according to Plaintiffs, it was Defendants' failure to disclose this communication to investors that rendered GPC's public statements about satraplatin false and misleading.[9] Accordingly, the Complaint will survive this motion only if the Court finds that Plaintiffs have pleaded this allegation with sufficient particularity to satisfy the stringent pleading standard established by the PSLRA and Fed. R. Civ. P. 9(b).

This Court is well familiar with this standard, including its requirement that the plaintiff "set forth the who, what, when, where and how of the alleged fraud." *Garber v. Legg Mason,*

[9] All of the GPC statements about which Plaintiffs complain appear to be challenged on the grounds that GPC failed to disclose that the FDA had rejected PFS as a basis for accelerated approval. *See, e.g.*, Cmp. ¶¶62, 63, 67-75, 77-78, 81, 85-86, 89-92, 94-95. Plaintiffs do not contend that the actual substance of these statements, (e.g., the number of patients enrolled in the SPARC trial as of a certain date, Cmp. ¶62) is false. Plaintiffs only identify two affirmative statements in GPC's 2005 20-F and 2006 20-F as potentially false, and these are statements that the FDA had agreed that PFS would be the primary endpoint for accelerated approval. Cmp. ¶¶72, 95. To the extent Plaintiffs try to claim that the challenged statements are false for some other reason, such a claim must be rejected. *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005) (dismissing securities fraud claims for failure to plead with sufficient particularity where "[p]laintiffs . . . set[] forth lengthy quotations from various releases . . . [but] neglect to make it clear what portion of each quotation constitutes a false representation.").

Inc., 537 F. Supp. 2d 597, 614 (S.D.N.Y. 2008).[10] Moreover, where the fraud claim rests, as it does here, on the proposition that the defendant failed to disclose material, adverse information, the plaintiff's allegation that the defendant possessed that information, if conclusory and unsupported by corroborating detail, is legally insufficient. To survive a motion to dismiss, the plaintiff must instead plead the factual basis for an assertion that the defendant was actually aware of the adverse information in question with enough particularity to persuade the Court that the plaintiff had a valid basis for the assertion. This requires the plaintiff to "***specifically identify*** the reports or statements containing this [adverse] information" and "cite the ***sources of data*** that indicate that the basis of the alleged omission existed." *Id.* at 615-16 (citation omitted) (emphasis added).

No matter how generously one construes the Complaint in this case, it falls well short of the pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b). Plaintiffs' allegation that the FDA told GPC that it would not grant accelerated approval of satraplatin if GPC were to use PFS as its primary endpoint – again, an allegation that the Court must credit if the Complaint is to survive Defendants' motion – could not be more conclusory. Plaintiffs do not set forth a single fact that would support the naked assertion that such a communication occurred. They do not identify how, when, or through what means the FDA's warning was conveyed to GPC. They do not say who participated in the communication or reveal the context in which it occurred. Plaintiffs identify no witnesses and cite no documents that contain or refer to that warning. The complete absence of any details about the communication, including details Plaintiffs would

[10] To comply with the PSLRA, the Complaint must allege facts that are "'sufficient to support a reasonable belief as to the misleading nature of the statement or omission.'" *Telenor East Inv. AS v. Altimo Holdings & Inv. Ltd.*, No. 07 Civ. 4829 (DC), --- F.R.D. ---, 2008 WL 782733, at *6 (S.D.N.Y. Mar. 25, 2008) (citation omitted). "'[B]ald contentions, unsupported characterizations, and legal conclusions are not well-pleaded allegations' and will not defeat the motion." *Id.* (citations omitted).

necessarily know if they had a basis for alleging that it occurred, reveals a great deal about the bona fides of Plaintiffs' claim and, more to the point, requires the Court to disregard this allegation in evaluating whether Plaintiffs have stated an actionable claim.

The Complaint contains only one allegation intended as support for Plaintiffs' assertion that the FDA warned GPC it would not grant accelerated approval based only on positive PFS results. Quoting from the Summary Minutes of ODAC's July 24, 2007 meeting,[11] Plaintiffs allege that, during that meeting, the ODAC "panel went out of its way to point out that the message that ***PFS would be unacceptable*** as a primary endpoint had been 'clearly communicated' to GPC during the development phase of the SPARC trial." Cmp. ¶17 (emphasis added). This allegation, however, is an objectively false characterization of the contents of the Summary Minutes. According to the Summary Minutes, the only thing that was "clearly communicated" to GPC during the development phase of the SPARC trial was that the FDA had "***no prior experience with*** the composite PFS endpoint GPC used for the trial."[12] Summary Minutes at 7 (emphasis added), Garbutt Aff., Exh. 9. Nothing in that document remotely suggests that the FDA advised GPC – or, for that matter, ever even believed – that PFS would be

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[11] For purposes of a motion to dismiss for failure to state a claim, a court may consider any part of a document cited in the complaint as well as SEC filings. *See Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1973 n.13 (2007) (on motion to dismiss, considering entirety of document referenced by plaintiff in complaint); *Garber*, 537 F. Supp. 2d at 607 n.1 & 610 (on motion to dismiss, court may consider the documents incorporated by reference into plaintiffs' pleadings and documents publicly filed with the SEC). Thus, in this motion to dismiss, it is appropriate for Defendants to rely on GPC's SEC filings, and the FDA documents, analyst reports, and press releases cited in the Complaint.

[12] The fact that the FDA said it was inexperienced with this composite endpoint obviously is fundamentally different from advice that they would never accept it as a basis for approval. Given the very nature of FDA review, the agency routinely encounters medical, scientific, and other complex issues of first impression. That being the case, the fact that GPC's NDA may have required the FDA to consider novel questions is neither unusual nor something that would raise serious doubts about approvability.

an unacceptable basis for accelerated approval of the NDA for satraplatin.[13] Thus, the allegation that is most fundamental to Plaintiffs' case is not just conclusory, it is also highly disingenuous.

B. The FDA Documents Cited in the Complaint Disprove Plaintiffs' Allegation that the FDA Rejected the PFS Endpoint as a Basis for Accelerated Approval.

The Complaint cites two FDA documents that shed light on the FDA's views of PFS and whether it could serve as an acceptable basis for granting accelerated approval of satraplatin: the Summary Minutes and the FDA Briefing Document prepared by the FDA in anticipation of that meeting. As noted, neither document supports Plaintiffs' allegation that the FDA objected to GPC's use of PFS and so advised GPC early in the development process.[14] Far more important, however, both documents on their face actually ***disprove*** the proposition that the FDA questioned the validity of a PFS endpoint as a basis for accelerated approval.[15] To the contrary, the only

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[13] The language quoted by Plaintiffs also appears in the FDA Briefing Document, Garbutt Aff., Exh. 8. That document, like the Summary Minutes, Garbutt Aff., Exh. 9, contains nothing suggesting either that the FDA believed PFS could not serve as a basis for accelerated approval, or that it ever said that to Defendants.

[14] Furthermore, the fact that the FDA accepted the NDA for filing, as well as its decision to allow a rolling submission of the application, belie the proposition that the FDA viewed PFS as an unacceptable basis for accelerated approval. The FDA's acceptance of an NDA for filing means that it believes the application has the potential to be approved without major modification. The FDA's regulations provide that "[t]he filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). The FDA may refuse to file an application if, among other things, the application is "incomplete because it does not on its face contain information required under section 505(b) . . . and § 314.50 . . ." 21 C.F.R. § 314.101(d)(3). Likewise, the FDA will permit a rolling submission of an application for a fast track product only if it determines "after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective . . ." 21 U.S.C. § 506(c)(1).

[15] *See, e.g.*, *In re Pfizer, Inc. Sec. Litig.*, 06 Civ. 14199(LAK) --- F. Supp. 2d ---, 2008 WL 540120, at *3-4 (S.D.N.Y. Feb. 28, 2008) (rejecting two of plaintiffs' allegations because the documents plaintiffs cited did not support their assertions, describing plaintiffs' characterization of a study as "misleading"); *In re Elan Corp. Sec. Litig.*, No. 05 Civ. 2860(RJH),--- F. Supp. 2d ---, 2008 WL 839744, at *12 (S.D.N.Y. Mar. 27, 2008) ("'[t]he court need not accept as true an allegation that is contradicted by documents on which the complaint relies'"), *quoting In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 555 (S.D.N.Y. 2004).

PFS-related question raised in either document was whether the ***particular definition of PFS*** used in the SPARC trial, being new to the FDA, should be accepted as a reliable measure of satraplatin's efficacy.[16]

Specifically, for purposes of the SPARC trial, PFS was defined as a "composite" endpoint that examined several different measures of disease progression, including radiographic progression (as indicated by bone scans), symptomatic progression (e.g., pain, weight loss and other clinical events related to prostate cancer), and skeletal-related events. Because the FDA had never before considered this particular composite definition of PFS, it was unsure whether to accept it as a reliable measure of the degree to which prostate cancer had progressed in the SPARC trial participants. In the FDA's words:

> The first issue is ***the definition of*** one of the two primary endpoints, PFS. PFS is ***defined as a composite endpoint***, consisting of radiographic progression, symptomatic progression (pain, analgesics, ECOG performance status, weight loss and other clinical events related to prostate cancer) and skeletal related events. The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase. FDA will seek ODAC advice on the acceptability of ***this*** composite PFS endpoint as the basis of marketing approval.

FDA Briefing Document at 3 (emphasis added), Garbutt Aff., Exh. 8.

In addition, the FDA Briefing Document specifically identifies PFS as the study's endpoint and nowhere suggests that the FDA was surprised by, or objected to, GPC's selection of that endpoint. And, under any fair reading of it, the overarching question being addressed in the FDA Briefing Document was ***not*** whether it would be appropriate to grant accelerated approval based on an endpoint that measured progression of the disease (*i.e.*, PFS), as opposed to

[16] The Complaint does not allege that the FDA alerted GPC to its concerns about GPC's composite definition of PFS before it released the FDA Briefing Document.

some other endpoint, such as overall survival. It was whether the specific PFS clinical trial results presented to the FDA, being the product of the "novel" composite endpoint used in the SPARC trial, were reliable evidence of the progression of HRPC in the study's participants.

Needless to say, if the FDA had categorically rejected the use of PFS for the SPARC trial, it would not have wasted its time analyzing the appropriateness of the particular definition of PFS used by GPC, nor would it have solicited ODAC's advice on this issue. Moreover, the fact that the FDA questioned only GPC's composite definition of PFS, rather than the validity of PFS as an endpoint generally, is confirmed by the fact that the FDA has repeatedly approved drugs on the strength of studies that used PFS as their endpoint. As noted in the analyst reports cited in the Complaint, "[a]lthough the composite endpoint [PFS] in the SPARC trial has not been used previously in registration trials, all of the [individual endpoints that were constituents of GPC's composite endpoint] each have been used in previous registration studies," and "PFS was accepted by the FDA . . . in other tumour indications" for other cancers. Deutsche Bank Analyst Report dated July 22, 2007 at 4, Garbutt Aff., Exh. 7; DZ Bank AG Analyst Report dated August 3, 2007 at 2 Garbutt Aff., Exh. 10. (referencing three other cancer drugs that were approved).[17]

In any event, it does not matter whether the concerns expressed in the FDA documents went to the use of the ***particular*** composite PFS endpoint GPC used or, instead, to the use of a PFS endpoint ***generally*** (*i.e.*, no matter how PFS is defined); the FDA Briefing Document

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[17] *See also In re Amgen, Inc. Sec. Litig.*, --- F. Supp. 2d ---, 2008 WL 999058, at *1 (C.D. Cal. Feb. 1, 2008) (referring to trial testing impact of drug on head and neck cancer that was measuring progression free survival and overall survival); *Watts v. Massachusetts Mut. Life Ins. Co.*, 892 F. Supp. 737, 740 (W.D.N.C. 1995) (referring to "primary efficacy endpoint of progression-free survival" in trial for drug to treat brain cancer); *Whitehead v. Federal Express Corp.*, 878 F. Supp. 1066, 1074 (W.D. Tenn. 1994) (referring to "progression-free survival" as objective of study of effect of drug on breast cancer).

establishes that those concerns, whatever their precise nature, ***did not*** lead the FDA to conclude that GPC's use of PFS was fatal to its prospects for obtaining accelerated approval. Instead, the FDA decided to "seek ODAC advice on the acceptability of this composite PFS endpoint as the basis of marketing approval." FDA Briefing Document at 3, Garbutt Aff., Exh. 8. This is further proof that the FDA clearly regarded PFS, if appropriately defined, as an acceptable basis for accelerated approval of satraplatin. Furthermore, according to the Summary Minutes, although the FDA did put this issue on the agenda for the July 24, 2007 ODAC meeting, the ODAC panel never even addressed the issue. The Summary Minutes state that "[d]ue to time constraints, Question 1 [whether PFS, as defined by GPC, was an acceptable primary endpoint] was not addressed by the committee." Summary Minutes at 8, Garbutt Aff., Exh. 9. Remarkably, Plaintiffs have built their entire case around an issue that proved to be irrelevant to the outcome of GPC's application for accelerated approval of satraplatin.

What the foregoing proves is that: (1) as late as July 2007, the FDA clearly regarded PFS as an acceptable basis for accelerated approval of a cancer drug, and was questioning only the reliability of the particular composite definition of PFS used in the SPARC trial; (2) despite its inexperience with the particular PFS definition used by GPC, the FDA never rejected even that definition as an appropriate basis for accelerated approval; and (3) according to the minutes of the ODAC meeting, the ODAC panel never addressed the appropriateness of GPC's definition of PFS before voting to delay action on GPC's application for accelerated approval of satraplatin. Consequently, GPC's use of that endpoint played no role in ODAC's decision to recommend delaying action on GPC's application.[18] Each of these incontrovertible facts is by itself

[18] GPC explicitly disclosed to investors that "although satraplatin is eligible for accelerated approval by the FDA, the FDA may not grant an accelerated approval if it concludes that the progression-free survival data and available overall survival data do not demonstrate that satraplatin provides *(cont.)*

sufficient to defeat Plaintiffs' claims.

C. The Claims Against the Individual Defendants For Statements They Did Not Personally Make Must Be Dismissed.

Yet another defect in the Complaint is its failure to make particularized allegations of false statements on the part of each of the individual Defendants. Plaintiffs instead impermissibly resort to the group pleading doctrine to avoid the requirement of separately identifying the allegedly fraudulent acts of each Defendant. Cmp. ¶38.

In the United States Supreme Court's recent decision in *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761 (2008), it held that defendants cannot be held liable for securities fraud based solely on alleged participation in a fraud. Where the plaintiff does not allege conduct by the defendants on which plaintiff relied or "fails to particularize any material misstatements or omissions by [certain individual] defendants," the claims against those defendants should be dismissed. *Katz v. Image Innovations Holdings, Inc.*, No. 06 Civ. 3707 (JGK), --- F. Supp. 2d ---, 2008 WL 762105, at *2 (S.D.N.Y. Mar. 24, 2008) (relying on *Stoneridge* to dismiss claims against three individual non-speaking defendants, who were current or former officers, directors or employees of the company).

Nor can Plaintiffs rely upon "group pleading" to have this Court treat group-published information, such as press releases, as the collective statements of the individual defendants

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a meaningful therapeutic benefit to patients over existing treatments or that the data are otherwise inadequate to support the granting of an accelerated approval due to weaknesses, inconsistencies or differences in the data with respect to data subsets or subpopulations in the treatment group." 2005 20-F at 5, Garbutt Aff. Exh. 1. GPC also disclosed that, even if the FDA were to grant accelerated approval of satraplatin, additional positive study results and/or data demonstrating improvement over placebo on overall survival would be needed for full approval. *See, e.g.*, *id.* at 5. In *Garber*, this Court rejected assertions that the defendants made material misstatements where, as here, the circumstances causing the plaintiffs' losses were the subject of explicit risk factors identified by the defendants. 537 F. Supp. 2d at 612-13, 615-17. The claims made here should be rejected for the same reason.

merely because they were officers of GPC. As this Court explained in *Ellison v. American Image Motor Co.*, "[w]hen fraud is alleged against multiple defendants, a plaintiff must plead with particularity by setting forth separately the acts complained of by each defendant. Rule 9(b) is not satisfied by a complaint in which defendants are clumped together in vague allegations." 36 F. Supp. 2d 628, 640-41 (S.D.N.Y. 1999) (internal punctuation and citations omitted).

Furthermore, the group pleading doctrine "cannot withstand the PSLRA's specific requirement that the untrue statements or omissions be set forth with particularity as to 'the defendant' and that scienter be pleaded with regard to 'each act or omission' sufficient to give 'rise to a strong inference that the defendant acted with the required state of mind.'" *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 364 (5th Cir. 2004) (citations omitted). The only Courts of Appeal that have specifically addressed the issue find that the group pleading doctrine did not survive enactment of the PSLRA. *Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007); *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 602-03 (7th Cir. 2006), *rev'd on other grounds*, 127 S. Ct. 2499 (2007); *Southland*, 365 F.3d at 364; *see also Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 184 (4th Cir. 2007); *Phillips v. Scientific-Atlanta, Inc.*, 374 F.3d 1015, 1018 (11th Cir. 2004). District courts within the Sixth, Eighth and Ninth Circuits have reached the same conclusion,[19] as did the court in *In re Cross Media Mktg. Corp. Secs. Litig.*, 314 F. Supp. 2d 256, 262 (S.D.N.Y. 2004).[20]

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[19] *See, e.g., In re United Am. Healthcare Corp. Sec. Litig.*, No. 2:05-CV-72112 (LPZ/RSW), 2007 WL 313491 (E.D. Mich. Jan. 30, 2007); *In re Hutchinson Tech. Inc. Sec. Litig.*, 502 F. Supp. 2d 884 (D. Minn. 2007); *Amgen*, 2008 WL 999058.

[20] Defendants are aware that courts within this district have held that the group pleading doctrine survived the passage of the PSLRA. *See, e.g.*, *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 439 (S.D.N.Y. 2005). Defendants disagree with these decisions.

Thus, because Plaintiffs do not identify any statement made by Maier or Meier-Ewert, all claims against them should be dismissed on this ground alone. Moreover, claims against Seizinger and Scherer must be limited to statements that each of them actually made, not statements of GPC or others.

II. THE COMPLAINT IS ALSO DEFECTIVE BECAUSE IT FAILS TO ALLEGE A CAUSAL CONNECTION BETWEEN DEFENDANTS' ALLEGED FRAUD AND THE LOSSES PLAINTIFFS CLAIM TO HAVE SUFFERED

A. The PSLRA Requires a Plaintiff to Plead a Clear Causal Connection Between the Alleged Fraud and the Shareholder Losses Alleged in the Complaint.

The PSLRA expressly provides that the "plaintiff shall have the burden of proving that the ***act or omission*** of the defendant . . . ***caused the loss*** for which the plaintiff seeks to recover." 15 U.S.C. § 78u-4(b)(4) (emphasis added). The courts have made it plain that the statute means what it says: a plaintiff must plead facts demonstrating a direct causal link between the alleged fraud and the loss the plaintiff claims to have suffered.

This Court correctly and succinctly articulated that loss causation requirement in its recent decision in *Garber* as follows:

> To state a Section 10(b) and Rule 10b-5 claim, plaintiffs must allege loss causation. *See Lentell,* 396 F.3d at 172. Loss causation is "a causal connection between the material misrepresentation and the loss." *Dura,* 544 U.S. at 342. "[A] plaintiff must allege ... that the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.,* that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Lentell,* 396 F.3d at 173 (quotation and citation omitted). "[I]f the connection is attenuated, or if the plaintiff fails to demonstrate a causal connection between the content of the alleged misstatements or omissions and the harm actually suffered, a fraud claim will not lie." *Id.* at 174 (quotations and citations omitted).

537 F. Supp. 2d at 616.

Last year, the Second Circuit also addressed the causation requirement in affirming the

dismissal of a securities fraud complaint in *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 106-07 (2d Cir. 2007), noting that a complaint must plead that the loss was foreseeable and caused by the materialization of the risk allegedly concealed by the fraud.[21]

B. The FDA Documents Cited in the Complaint Demonstrate That There Was No Causal Connection Between the Harm Alleged by Plaintiffs and Defendants' Alleged Nondisclosure of the FDA's Concerns About the Suitability of PFS.

Rather than establishing a causal connection between Defendants' alleged fraud and the drop in GPC's share price, the Complaint affirmatively demonstrates the absence of such a connection. The FDA documents on which it relies clearly show that, even if, unbeknownst to GPC shareholders, the FDA had advised GPC early on that it would not grant accelerated approval based only on a PFS endpoint, the outcome for those shareholders would have been the same. This is true for two reasons.

First, if, as Plaintiffs allege, the FDA at one time considered PFS to be an unacceptable endpoint, it obviously reversed its position by the time it released the FDA Briefing Document. As noted above, that document rules out the possibility that the FDA was unwilling to grant approval based only on PFS study results and makes plain that, insofar as it had concerns about GPC's endpoint, they related only to the particular composite PFS definition used in the SPARC trial. And, again, the FDA Briefing Document proves that the FDA considered granting accelerated approval – even on the basis of GPC's composite PFS endpoint – because it shows

[21] The seminal case on the causation requirement is *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336 (2005). In *Dura*, the United States Supreme Court reversed the Court of Appeals' holding that loss causation had been established, reasoning that the drop in the issuer stock price was "principally due to slow drug sales" rather than by allegedly false statements about the prospects of obtaining FDA approval of an asthmatic spray device. The Court stressed that it is essential that the plaintiffs show a causal connection between the misrepresentation and the alleged harm suffered by investors because private actions under the securities statutes are "not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations ***actually cause.***" *Id.* at 345 (emphasis added).

that the FDA's decision was to seek ODAC's advice on the issue rather than reject the application outright.

Second, even if the FDA had been reluctant to grant approval based on PFS (however it is defined), that reluctance did not cause either the drop in GPC's stock price following release of the FDA Briefing Document or the one triggered by ODAC's vote to defer action on GPC's application until after the FDA obtained final overall survival data.

As for the former, the PFS issue was only one of five approvability issues raised in the FDA Briefing Document. One can not reasonably conclude that, if the FDA had mentioned only the four other issues, GPC's stock price would have been unaffected. Likewise, it is beyond dispute that the FDA's concern about the composite PFS definition played absolutely no role in ODAC's vote to delay action on GPC's application and in the decline in stock price precipitated by that vote. As noted above, although the appropriateness of PFS as defined by GPC was identified as one of the issues on which FDA sought ODAC advice, the Summary Minutes state that "[d]ue to time constraints, [this issue] was not addressed by the committee." Summary Minutes at 8, Garbutt Aff., Exh. 9. Consistent with this fact, the Summary Minutes attribute ODAC's vote to defer action on GPC's application to other factors. Among them were:

- ODAC's concern that "radiologic progress was not reliably assessed [and] the number of radiology assessments confounded the actual results of the study."
- ODAC's view that the "the pain model used in the trial did not meet the standard for adequately assessing pain."
- The interim (not final) survival analysis in the SPARC trial suggested that satraplatin was no better than placebo and was less effective than docetaxel, another prostate cancer drug approved by the FDA after the SPARC trial had begun.

Summary Minutes at 8-9.

The Complaint does not allege, nor could it, that GPC had reason to predict that ODAC

would be concerned about these issues or that those concerns would delay approval of GPC's application. It follows that the circumstances resulting in ODAC's vote were unrelated to the fraud alleged in the Complaint and, thus, that fraud could not have been the cause of Plaintiffs' losses.

III. PLAINTIFFS' SCIENTER ALLEGATIONS ARE LEGALLY INSUFFICIENT BECAUSE THEY DO NOT GIVE RISE TO A STRONG INFERENCE OF SCIENTER

A. The Pleading Standard Governing Scienter Allegations.

"To satisfy the Rule 9(b) and PSLRA pleading requirements with respect to scienter, Plaintiffs must allege facts giving rise to a 'strong inference' of fraudulent intent." *Garber,* 537 F. Supp. 2d at 615 (citation omitted). "The requisite intent may be established either by alleging facts (1) showing that defendants had both motive and opportunity to commit fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* Circumstantial evidence of conscious behavior or recklessness has been defined as "deliberate illegal behavior" and "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care." *Id.* at 616 (citation omitted).

In addition, on a motion to dismiss, the Court should consider "whether ***all*** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007) (emphasis in original). For an inference of fraudulent intent to qualify as "strong," it "must be cogent and at least as compelling as any opposing inference of nonfraudulent intent"; an inference that is merely plausible or reasonable is not enough. *Id.* This means a court "must engage in a comparative evaluation," and "must consider, not only inferences urged by the plaintiff, … but also [plausible] competing inferences rationally drawn from the facts alleged." *Id.* at 2504. The question on a motion to dismiss is whether the plaintiff

has pled "facts rendering an inference of scienter ***at least as likely as*** any plausible opposing inference." *Id.* at 2513 (emphasis in original). Plaintiffs have failed to meet these stringent requirements here.

B. Plaintiffs' Allegations of Conscious Misbehavior Are Inadequate as a Matter of Law.

1. Plaintiffs Have Not Sufficiently Pled Defendants' Actual Knowledge of Undisclosed Adverse Information.

Plaintiffs' contention that Defendants engaged in conscious misbehavior relies almost entirely on their allegation that Defendants "knew from the start of the Class Period that they had selected an endpoint for the SPARC trial that would not lead to fast track FDA approval for satraplatin, but hid that information to allow them to simultaneously raise money from unsuspecting investors and to sell their personal holdings for huge profits."[22] Cmp. ¶118. Defendants have already addressed in this memorandum the many reasons this allegation is legally insufficient to establish fraudulent conduct on Defendants' part. *See* Argument, §§ I.A-B, *supra*. For the same reasons, this allegation will not support an inference of scienter, let alone a strong one. "If the facts alleged in the Complaint are insufficient to support Plaintiffs' belief that false or misleading statements were made, those facts cannot support an inference that Defendants knew or should have known their statements were false or misleading when Defendants made them." *Pfizer*, 2008 WL 540120, at *9 (citation and internal punctuation omitted).[23]

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[22] Plaintiffs have not alleged, even in conclusory fashion, that defendants acted recklessly, and, for the same reasons discussed in this section, the facts they alleged could not support such an assertion.

[23] Plaintiffs cannot base an inference of scienter on their suggestion that the drug approval process is a certain and predictable process with "established" or "accepted endpoints" that were simply ignored by GPC. Cmp. ¶¶ 55, 57. As with Plaintiffs' characterization of the FDA documents, this assertion is simply wrong. *See, e.g.*, *Lasalle v. Medco Research, Inc.*, 54 F.3d 443, 445 (7th Cir. 1995) ("Everyone knows that the process of obtaining the FDA's approval for a new drug is

(cont.)

The PSLRA requires Plaintiffs to allege facts giving rise to a strong inference of scienter as to ***each*** Defendant in this case. And, because the fraud they allege involved a failure to disclose material adverse information about the approvability of satraplatin, Plaintiffs must specifically allege, as to ***each*** Defendant, particularized ***facts*** (*i.e.*, particular documents, particular meetings, particular information, particular witness accounts, etc.) that "indicate that the basis of the alleged omission existed." *Garber*, 537 F. Supp. 2d at 616. "Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports[,] statements [or other source of] this information." *Id.* at 615.

The Complaint, however, contains no such allegations. Instead, as noted above, it asserts without elaboration only that the FDA "told" Defendants that PFS would not suffice, *e.g.* Cmp. ¶12, or that Defendants "knew" that PFS had been rejected, *e.g.* Cmp. ¶¶63, 96, 117, as an endpoint, but it contains no facts to support these bald assertions, such as when Defendants were told, which Defendant(s) (or any other GPC representative, for that matter) the FDA told, where and when the FDA told them, or how each Defendant otherwise knew this. Instead, Plaintiffs fall back on the boilerplate assertion that, by virtue of their "positions with the Company, they had access to the adverse undisclosed information … ." *E.g.*, Cmp. ¶37. That is not, however, a permissible means of pleading scienter because "general allegations that insiders had access to confidential information are insufficient." *Xerion Partners I LLC v. Resurgence Asset Mgmt., LLC*, 474 F. Supp. 2d 505, 518 (S.D.N.Y. 2007). Therefore, dismissal of the claims against all of the individual Defendants is required.

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fraught with uncertainty."); *Bristol-Myers Squibb*, 312 F. Supp. 2d at 562 (noting "the uncertainty inherent in any application for FDA approval"); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966-67 (D. Md. 1995) (disagreement with FDA over interpretation of test results does not mean defendants' beliefs about approvability were not reasonable).

2. GPC's Warnings to Investors Undercut Any Inference of Conscious Misbehavior.

Where defendants warn investors about the risk about which plaintiffs claim to have been misled, any otherwise conceivable inference that the defendant consciously hid information is weakened. Here, GPC's warnings to investors about the possibility of the very outcome that led to their losses seriously undermine an inference that Defendants sought to deceive those investors. *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 8 (1st Cir. 2006) ("attempts to provide investors with warnings of risks generally weaken the inference of scienter"); *In re Loral Space & Communications Ltd. Sec. Litig.*, No. 01 Civ. 4388 (JGK), 2004 WL 376442, at *10 (S.D.N.Y. Feb. 27, 2004) (warnings "undercut plaintiffs' speculation that the defendants were consciously attempting to defraud investors").[24]

C. Plaintiffs' Allegations that Defendants had a Motive to Commit Fraud Fail as a Matter of Law.

Although Plaintiffs allege several possible motives in support of their scienter accusation, none of them is satisfactory under applicable law.

1. Plaintiffs Have Not Alleged Scienter by Asserting Motives Generally Possessed by Most Corporations, such as Marketing a Product before Patents Expire or Raising Capital.

Neither Defendants' alleged motive to market satraplatin before its patent protection expired, nor their motive to raise capital support Plaintiffs' scienter allegations because both such motives are of the sort "generally possessed by most corporate directors and officers" and simply

[24] The resignations of Scherer, Maier and Meier-Ewert in late 2007 and early 2008, Cmp. ¶¶22, 115-16, are irrelevant to the scienter analysis. *See Communications Workers of Am. Plan for Employees' Pensions & Death Benefits v. CSK Auto Corp.*, 2007 WL 951968, at *6 (D. Ariz. Mar. 28, 2007) ("Neither a resignation nor a termination by itself gives rise to a strong inference of scienter.") (internal citations omitted); *Xerion Partners*, 474 F. Supp. 2d at 519 (rejecting argument that defendant's resignation four months after alleged wrongdoing was indicative of scienter).

"do not suffice" to allege scienter. *Kalnit v. Eichler,* 264 F.3d 131, 139 (2d Cir. 2001).

a. Defendants' alleged concern about the loss of patent protection does not establish a motive to commit fraud.

Plaintiffs assert that GPC was bent on obtaining accelerated approval of satraplatin for fear that it had only a limited and shrinking window of time to commercially exploit the drug before its patents expired, thereby exposing GPC to competition by generic pharmaceutical companies. Cmp. ¶4. However, even the Complaint acknowledges that one of the patents was valid until 2010. Cmp. ¶¶4, 49; *see also* 2005 20-F at 6, Garbutt Aff., Exh. 1; 2006 20-F at 8, Garbutt Aff., Exh. 2. Plaintiffs provide no facts to support their contention that "[i]f GPC went through the standard FDA procedure, patent protection for the drug would expire [in 2010] before regulatory approval could be obtained." Cmp. ¶4.

Further, as GPC explained, if satraplatin were approved, it would receive five years of data exclusivity as a "new chemical entity" under the Hatch-Waxman Act. 2005 20-F at 47; *accord* 2006 20-F at 48. This exclusivity applies regardless of whether the patents covering satraplatin had any remaining life. 21 U.S.C § 355(c)(3)(E)(ii) & 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2). *See also* 2005 20-F at 47. "Five year NCE [new chemical entity] data exclusivity prohibits the FDA from accepting [another application] for a drug product containing the same active moiety for a five-year period beginning on the date of the approval of the NDA." 2005 20-F at 47. *Accord* 2006 20-F at 49. Thus, as revealed in GPC's 2005 and 2006 20-F Reports, Defendants understood that no matter when satraplatin was approved, it would enjoy at least five years of marketing exclusivity under the Hatch-Waxman Act. Even the Complaint acknowledges that if regulatory approval was obtained, "[a]n extension to the exclusivity period provided by these patents was possible." Cmp. ¶49.

In any case, the Complaint's allegations that Defendants were motivated to pursue

accelerated approval "to address potential concerns about patent expirations" are "nothing more than ordinary and prudent corporate desires" that are insufficient to allege a motive to commit securities fraud. *Bristol-Myers Squibb*, 312 F. Supp. 2d at 560-61; *see also Pfizer*, 2008 WL 540120, at *2, *8 (court found that the desire to obtain a new blockbuster drug in the face of patent expirations "is not a unique motive. Rather, it is a way of saying, in a manner tailored to a pharmaceutical company, something that is true for all profit enterprises – each has an incentive to portray the likelihood that it will continue to prosper.").

b. A desire to raise capital is not a legally sufficient motive.

Nor do Plaintiffs allege a legally sufficient motive by asserting that the purported fraud "allowed the cash-starved company to raise new funds." Cmp. ¶64; *see also* Cmp. ¶¶16, 68, 69, 74, 81.

First, in its 2005 20-F, GPC reported that the Company believed it had "sufficient" amounts "to fund our anticipated operating requirements for at least the next 18 months." 2005 20-F at 10, Garbutt Aff., Exh. 1. The Complaint contains no facts calling into question the accuracy of that statement.

Second, allegations that a company was motivated to raise capital are also legally insufficient to allege motive. For example, in *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CivA-04CV-1030-RPM, 2005 WL 4161977, at *12 (D. Colo. Oct. 20, 2005), the court rejected the plaintiff's attempt to plead motive based on claims that a biopharmaceutical company "was depleting its cash supply at a rapid rate and needed to raise capital through a private placement." The court explained that "[t]he plaintiff's allegations about the [the company's] private placement adds little to the determination of scienter. In the absence of allegations of particularized facts about defendants' actual motives, the fact that a corporation engaged in financing activities during the alleged class period does not create a strong inference of

fraudulent intent." *Id.* at *13; *accord San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 813 (2d Cir. 1996) (desire to maximize securities offering does not qualify as sufficient motive); *Elan*, 2008 WL 839744, at *21 ("Any corporation would be motivated to . . . "finance the successful launch of a promising product.")

2. The Stock Sales Do Not Adequately Allege Motive.

Plaintiffs also allege that individual Defendants' stock sales evidence a motive to commit fraud. *See, e.g.*, Cmp. ¶¶6, 16, 22. This argument fails as well because those sales were made pursuant to pre-arranged trading plans, and because Plaintiffs have not met their burden to show the sales were unusual.

a. The insider sales on which Plaintiffs rely were made pursuant to Rule 10b5-1 statutory trading plans.

Plaintiffs allege that all the stock sales referenced in the Complaint were pursuant to pre-arranged trading plans. Cmp. ¶¶66, 80, 100. Stocks sold pursuant to such plans provide insiders with an affirmative defense to claims of insider trading. 17 C.F.R. § 240.10b5-1(c)(i). "[I]t is a defense to an allegation of violation of Section 10b and Rule 10b5-1, if the person making the purchase or sale demonstrates that the purchase or sale that occurred was made pursuant to a plan." *SEC v. Healthsouth Corp.*, 261 F. Supp. 2d 1298, 1322 (N.D. Ala. 2003); *see also In re Miva, Inc. Sec. Litig.*, No. 05-201- FtM-29DNF, 2008 WL 450037, at *6 (M.D. Fla. Feb. 15, 2008) (Trades "done pursuant to a Rule 10b5-1 Trading Plan . . . rebut[] any possible inference of scienter from the stock sales."). Although Plaintiffs assert that the individual Defendants should be denied the statutory protection that attaches to their plans because they knew, but failed to disclose, that the FDA had warned it would not accept PFS as a primary endpoint, that assertion should be disregarded by the Court because it is entirely conclusory, as set forth in Argument, §I.A *supra*.

b. Plaintiffs have not alleged that the stock sales were unusual in timing or amount.

"[E]xecutive stock sales, standing alone, are insufficient to support a strong inference of fraudulent intent." *Bristol-Myers Squibb*, 312 F. Supp. 2d at 561. Instead, Plaintiffs bear the burden of demonstrating that the insider stock trading was "unusual." *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995). The factors a court considers to determine whether trading activity is "unusual" include, *inter alia*, "the amount of profit from the sales, [and] the portion of stockholdings sold." *In re Scholastic Corp Sec. Litig.*, 252 F.3d 63, 74-75 (2d Cir. 2001). Plaintiffs have not met their burden of showing that the sales of GPC stock were unusual because they have not alleged: (1) the amount of profits from the sales (only the gross proceeds), *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 445 (S.D.N.Y. 2005); (2) the portions of the individual Defendants' stockholdings that were sold (only the amounts sold), *Scholastic*, 252 F.3d at 76 (the "dollar amount cannot be considered in isolation"); *Malin v. XL Capital Ltd.*, 499 F. Supp. 2d 117, 153 (D. Conn. 2007) (large stock sales are not probative of scienter unless they are significant compared to the insider's total holdings); or (3) facts showing that the timing of all of the sales was suspicious.

"[I]nsider trading is suspicious only when it is 'dramatically out of line with prior trading practices ***at times calculated to maximize the personal benefit*** from undisclosed inside information.'" *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (emphasis added). Plaintiffs' allegations here do not show that the timing of many of the challenged stock sales was suspicious. The class period alleged by Plaintiffs begins on December 5, 2005 and ends on July 24, 2007, a period of eighty-five weeks. A class period so lengthy "weakens any inference of scienter that could be drawn from the timing of defendants' trades." *Malin*, 499 F. Supp. 2d at 151 (internal quotes omitted) (102 week alleged class period); *see also In re Vantive*

Corp. Sec. Litig., 283 F.3d 1079, 1092 (9th Cir. 2002) (an alleged class period of 63 weeks is "unusually long").

Plaintiffs have not sufficiently averred that all the individual Defendants' stock sales were timed to maximize their personal benefit. To the contrary, Plaintiffs identify thousands of shares sold by each individual Defendant in December 2005 and January 2006 at prices that are roughly ***half*** the prices at which sales occurred near the end of the putative class period. *Compare* Cmp. ¶65 (prices ranging from 10.54 to 11.26 euros) *with* Cmp. ¶99 (prices ranging from 19.19 to 22.94 euros). It would be nonsensical for the individual Defendants to sell early in the putative class period when the potential for much higher profits existed later. Nor are the sales in September and October 2006 at prices from 14.92 to 16.43 euros consistent with a fraud designed to maximize personal benefits. Cmp. ¶79. *In re Openwave Sys. Sec. Litig.*, 258 F. Supp. 2d 236, 251-52 (S.D.N.Y. 2007) (sales "well below the class-period high price" did not support an inference of scienter).

In short, viewing all the Complaint's allegations in context, Plaintiffs have failed to plead facts supporting an allegation of scienter that is at least as cogent, likely and compelling as an opposing inference of non-fraudulent intent.

IV. PLAINTIFFS' CONTROL PERSON CLAIM FAILS

A. Plaintiffs' Section 20(a) Claim Cannot Stand Because the Underlying Violations of the Securities Laws are Inadequately Pled.

As an initial matter, the Section 20(a) claim should be dismissed because Plaintiffs fail to state claims under Section 10(b), and thus, the control person claim must fail as well. *See SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472-73 (2d Cir. 1996); *ATSI*, 493 F.3d at 108.

B. Plaintiffs' Control Person Claim Fails because They have Not Adequately Shown That Any Individual Defendant Was a Culpable Participant in the Alleged Fraud.

Even assuming a valid Section 10(b) claim, the control person claim should still be dismissed because the Complaint does not plead all the elements of a Section 20(a) violation. "To establish a prima facie case of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI*, 493 F.3d at 108 (*citing First Jersey*, 101 F.3d at 1472); *Garber*, 537 F. Supp. 2d at 618 ("Section 20(a) claims must allege 'culpable participation.'") (citation omitted).

Furthermore, Plaintiffs must plead the allegations of culpable participation ***with the same particularity*** as scienter under Section 10(b). *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 246-47 (S.D.N.Y. 2006). Plaintiffs "must plead with particularity facts giving rise to a strong inference that the controlling person knew or should have known that the primary violator, over whom that person had control, was engaging in fraudulent conduct." *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 660-61 (S.D.N.Y. 2007).

As amply demonstrated above, Plaintiffs fail to allege any culpable conduct on the part of the individual Defendants, let alone any culpable participation, with the heightened particularity required by the Second Circuit. Therefore, the Section 20(a) claim should be dismissed.

V. PLAINTIFFS' SECTION 20A CLAIM ALSO FAILS AS A MATTER OF LAW

A. Plaintiffs Have Not Alleged an Underlying Violation of the Exchange Act.

Under Section 20A, a plaintiff must plead, first and foremost, "a predicate violation of the [Exchange] Act or its rules and regulations." *Jackson Nat'l Life Ins. Co. v. Merrill Lynch & Co.*, 32 F.3d 697, 703 (2d Cir. 1994). For the reasons stated in Argument, §§ I-III, *supra*, Plaintiffs have failed to plead any such violation, and the Section 20A claim should be

dismissed.

B. Plaintiffs Have Not Alleged the Contemporaneous Trades Required by Section 20A.

Even assuming a primary violation of the Exchange Act, Section 20A provides relief only to those "who, contemporaneously with the purchase or sale of securities that [are] the subject of [the] violation, ha[ve] purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities) securities of the same class." 15 U.S.C. § 78t-1(a). Plaintiffs must plead this "contemporaneous transaction" with specificity. *Openwave*, 528 F. Supp. 2d at 256 n.10 (the heightened pleading requirements of the PSLRA and Rule 9(b) appear to apply to claims brought under Section 20A); *see also Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993) (holding that specificity requirements applied to claim of insider trading); *In re Federal Nat'l Mortgage Ass'n Sec., Derivative, and "ERISA" Litig.*, 503 F. Supp. 2d 25, 46 (D.D.C. 2007) (holding that specificity requirements applied to Section 20A claim).

The purpose underlying Section 20A is to serve "as a proxy for the traditional requirement of contractual privity between plaintiffs and defendants." *In re AST Research Sec. Litig.*, 887 F. Supp. 231, 233 (C.D. Cal. 1995). The time frame between an insider's sale and a plaintiff's purchase must be relatively short to ensure the possibility that the plaintiff purchased the actual shares sold by the insider. As the time between the sale and purchase increases, the likelihood that the plaintiff purchased the insider's shares decreases substantially. *Id.*

The Second Circuit has not ruled on how close in time the two trades must be to satisfy the requirement that they be contemporaneous. Two decisions from within this district find that five trading days was a reasonable interval between the insiders' sales and investors' purchases in order for them to be considered contemporaneous. *In re Take-Two Interactive Sec. Litig.*, No.

06 CV. 803(SWK), 2008 WL 1757823 (S.D.N.Y. Apr. 16, 2008); *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133 (S.D.N.Y. 1999).[25] The majority of courts to address the issue, however, have taken a narrower view of the contemporaneous requirement. *See Federal Nat'l Mortgage Ass'n*, 503 F. Supp. 2d at 46-47 (collecting cases). Thus, many courts have held that the defendant's trades must take place ***after*** the insider's sale, *In re Enron Corp. Sec., Derivative & "ERISA" Litig.*, 258 F. Supp. 2d 576, 600 (S.D. Tex. 2003), and occur on the ***same*** day. *See, e.g.*, *In re MicroStrategy, Inc. Sec. Litig.*, 115 F. Supp. 2d 620, 664 (E.D. Va. 2000); *Copland v. Grumet*, 88 F. Supp. 2d 326, 338 (D.N.J. 1999). Courts have rejected claims where it was apparent that the parties could not have actually traded with each other, holding that a three day trading lapse defeats the contemporaneous requirement. *Buban v. O'Brien*, No. C 94-0331, 1994 WL 324093, at *3 (N.D. Cal. June 22, 1994) ("It is manifest that plaintiff could not have traded with defendant" where they traded three days apart at different prices and where numerous shares changed hands every day.)

In this case, none of Lead Plaintiff's purchases satisfies the contemporaneous requirement, as none of its purchases were on the same day and after any of individual Defendants' sales. Plaintiff Chua's June 12, 2007 purchase occurred the same day as one of Maier's sales. Plaintiffs have not pled any other contemporaneous transactions. As to that one transaction, Plaintiffs have not shown how Chua's purchase of American Depositary Shares on the NASDAQ constitutes a purchase of "securities of the same class" as Maier's sale of Ordinary Shares on the Frankfurt Stock Exchange. Therefore, Plaintiffs' Section 20A claims should be dismissed.

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[25] In *Oxford*, plaintiffs purchased shares on 21 of the 25 days on which the defendants sold such shares, and the five day trading lapse found to be sufficiently contemporaneous only applied to the remaining four trading days of defendants. In other words, the bulk of the Section 20A claim consisted of same-day contemporaneous sales.

CONCLUSION

For all the reasons set forth above, Defendants' motion to dismiss the Complaint herein should be granted in its entirety.

Dated: New York, New York
May 14, 2008

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